DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FEB 14 2002

Re: CeeOn Model 911A
Docket No. 01E-0404

The Honorable Q. Todd Dickinson
Director of U.S. Patent and Trademark Office
Commissioner for Patents
Box Pat. Ext.
Washington, D.C. 20231

Dear Director Dickinson:

This is in regard to the application for patent term extension for U.S. Patent No. 5,444,106 filed by Pharmacia AB under 35 U.S.C. § 156. The medical device claimed by the patent is CeeOn Model 911A (high refractive index silicone compositions), which was assigned premarket approval application (PMA) No. P990080.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in *Glaxo Operations UK Ltd. v. Quigg*, 706 F. Supp. 1224 (E.D. Va. 1989), *aff'd*, 894 F. 2d 392 (Fed. Cir. 1990).

The PMA was approved on April 5, 2001, which makes the submission of the patent term extension application on June 4, 2001, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Holly D. Kozlowski
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